

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: U.S. Patent No. 5,061,703

Inventors: Joachim BORMANN, Markus GOLD, and Wolfgang SCHATTON

Assignee: Merz Pharma GmbH & Co. KGaA

Title: ADAMANTANE DERIVATIVES IN THE PREVENTION AND TREATMENT OF CEREBRAL ISCHEMIA

Issue Date: October 29, 1991

**SECOND SUPPLEMENT TO REQUEST
FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. § 156**

Mail Stop Hatch-Waxman PTE
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This supplement relates to the pending request for extension of the term of U.S. Patent No. 5,061,703 ("the '703 patent") pursuant to 35 U.S.C. § 156, which was submitted on December 9, 2003 by Forest Laboratories, Inc. ("Forest") acting as agent of the patent owner Merz Pharma GmbH & Co. KGaA ("Merz"). The USPTO has stated that, subject to final review, the '703 patent "is considered eligible for patent term extension." *See* February 28, 2007 Letter from USPTO to FDA regarding NAMENDA™ (memantine hydrochloride).

A first supplement to the December 9, 2003 Request was filed on December 27, 2006 to indicate that the '703 patent had been reexamined by the USPTO, and to provide a copy of the Certificate of Reexamination that issued on November 7, 2006. As stated in the first supplement, the reexamination proceeding resulted in the amendment of claims 1 and 10, confirmation of the patentability of claims 2-9 and 11-13, and addition of claims 14-19.

Pursuant to 37 CFR 1.765, this supplement is submitted to indicate that claims 14-19, which were added during the reexamination proceeding, cover methods of using NAMENDA™ (memantine hydrochloride) for the treatment of moderate to severe dementia of the Alzheimer's type, for which NAMENDA™ has been approved. Thus, in addition to claims 1 and 10, other claims that cover the approved method for using the approved product include claims 2, 3, 6, 8, and 11-19.

The patent owner, Merz, hereby requests that the Commissioner grant an extension of 1250 days to U.S. Patent No. 5,061,703.

Favorable action is earnestly solicited.

Dated: November 13, 2008

Respectfully submitted,

By

S. Peter Ludwig
Registration No.: 25,351
DARBY & DARBY P.C.
P.O. Box 770
Church Street Station
New York, New York 10008-0770
(212) 527-7700
(212) 527-7701 (Fax)
Attorneys/Agents For Applicant